IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BTL INDUSTRIES, INC., Plaintiff, v. ALLERGAN PLC, ALLERGAN USA, INC., ALLERGAN, INC., and ZELTIQ AESTHETICS, INC., Defendants.	
ZELTIQ AESTHETICS, INC., Counterclaim-Plaintiff, v. BTL INDUSTRIES, INC., Counterclaim-Defendant.	C.A. No. 1:20-cv-00239-CFC

DEFENDANT ZELTIQ AESTHETICS, INC.'S COUNTERCLAIMS, ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT

Defendant Zeltiq Aesthetics, Inc. ("Zeltiq"), by and through its undersigned counsel, hereby answers the Complaint (the "Complaint") filed by Plaintiff BTL Industries, Inc. ("BTL"), and counterclaims against BTL as follows.

PRELIMINARY STATEMENT

This lawsuit is a baseless attempt by BTL to stifle fair competition in the medical aesthetics market. Zeltiq is a longtime market leader, having launched its CoolSculpting fat reduction product in 2010. Zeltiq has built strong relationships over the years with dermatologists, plastic surgeons and other aesthetics healthcare professionals (together, "HCPs"). In June 2019, Zeltiq announced its CoolTone magnetic stimulation system. CoolTone is cleared by the Food and Drug Administration ("FDA") for strengthening, toning and firming muscles in the abdomen, buttocks and thighs. A large number of HCPs, building on their trust in CoolSculpting and their longstanding relationship with Zeltiq, have embraced CoolTone as an exciting and affordable alternative to BTL's Emsculpt system. Patient satisfaction with CoolTone has likewise been high. BTL now resorts to this litigation, and an equally baseless patent lawsuit, to try to disrupt CoolTone's fairly earned market success.

Zeltiq's advertising for CoolTone has been entirely fair, accurate and well-supported. In advertising to HCPs, Zeltiq has featured some of CoolTone's technical specifications – including the true assertion, supported by third-party and in-house testing, that "CoolTone has 50% more magnetic intensity than the leading competitor, measured in tesla (T) at the point of patient contact." Zeltiq has paired that assertion with the clear disclaimer that the "clinical significance of [magnetic

intensity] data has not been established." In advertising to prospective patients, Zeltiq has made different claims – none of which BTL challenges in this lawsuit, and none of which cite to magnetic intensity or similar technical specifications of CoolTone.

The real cause for concern in the aesthetics market is BTL's own advertising for Emsculpt, which is riddled with falsehoods. BTL distorts, misstates and overstates what Emsculpt is approved to do and what it can do, and it falsely and knowingly disparages Zeltiq and its CoolSculpting and CoolTone products. In particular, BTL promotes mere technical specifications of Emsculpt as causing performance benefits – ironically, doing itself exactly what it incorrectly accuses Zeltiq of doing. BTL exaggerates and distorts the capacity of Emsculpt to reduce fat, a usage for which Emsculpt is not cleared or approved by the FDA. BTL also makes a wide range of egregiously false claims of health and athletic performance benefits for Emsculpt – promising patients everything from faster marathon times to better golf scores. Zeltiq hereby counterclaims against BTL, in order to protect itself, HCPs and patients from the consequences of BTL's false advertising.

COUNTERCLAIMS

1. Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendant Zeltiq Aesthetics, Inc. ("Counterclaimant" or "Zeltiq") hereby demands a jury trial and asserts against Plaintiff BTL Industries, Inc. ("Counter-defendant"

or "BTL") the following counterclaims for false advertising in violation of the Lanham Act (15 U.S.C. § 1125(a)(1)(B)) and Delaware's Deceptive Trade Practices Act (6 *Del. C.* § 2532) ("DTPA").

THE PARTIES

2. Counterclaimant Zeltiq is a corporation organized and existing under the laws of Delaware with its principal place of business at 2525 Dupont Dr., Irvine, California 92612.

3. Upon information and belief, Counter-defendant BTL Industries, Inc. is a privately held corporation organized and existing under the laws of Delaware with a principal place of business at 362 Elm Street, Marlborough, Massachusetts 01752.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over Zeltiq's Counterclaims in accordance with 28 U.S.C. §§ 1338 and 1331, and 15 U.S.C. § 1121.

5. This Court has jurisdiction over Zeltiq's State law claim pursuant to 28 U.S.C. § 1367.

6. This Court has personal jurisdiction over BTL because BTL has submitted itself to this Court's jurisdiction for purposes of this action concerning false advertising claims with respect to Zeltiq. In addition, on information and belief, BTL (i) conducts business and specifically sells its Emsculpt product in

Delaware and within this district, (ii) has engaged in acts or omissions within Delaware causing injury, (iii) has engaged in acts or omissions outside of Delaware causing injury within Delaware and (iv) has otherwise made or established contacts within this State sufficient to permit the exercise of personal jurisdiction.

7. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) as a substantial part of the events giving rise to the Counterclaims alleged herein occurred in this judicial district.

BACKGROUND

8. BTL's advertising for Emsculpt persistently misstates what Emsculpt can do or is approved to do. BTL falsely advertises a wide range of tangible, specific purported benefits that are not supported by Emsculpt's FDA clearances, by published studies or by anything else:

- BTL falsely and explicitly claims that alleged technical specifications of Emsculpt – such as its purported "higher output" and "more energy" – will deliver "better and faster results." That is exactly what BTL incorrectly accuses Zeltiq of doing – a classic case of the pot calling the kettle black.

- BTL's approach is the opposite of Zeltiq's careful and lawful advertising. By policy, Zeltiq directs its advertising of technical specifications only to healthcare professionals; avoids linking technical specifications to efficacy benefits; and states in a clear disclaimer that the clinical significance of CoolTone's greater magnetic intensity has not been established. BTL respects no such limitations: It falsely touts the technical specifications of Emsculpt, to

doctors and patients alike, explicitly equating those specifications with unsupportable efficacy claims and without any disclaimer.

- BTL routinely promotes Emsculpt for fat reduction – a benefit for which it is not FDA-approved and for which there is no reliable published clinical support.

- BTL claims Emsculpt will improve athletic performance and physical health in numerous specific ways, even asserting that Emsculpt will lead to improved race times for marathoners and lower scores for golfers. None of these benefits is legitimate or supported by any published study. None has been recognized by the FDA in its clearances of Emsculpt.

9. These claims by BTL deceive doctors and patients, injure Zeltiq and egregiously violate the laws against false advertising. Zeltiq asks the Court to stop BTL in order to ensure that doctors and patients are protected against future false advertising of BTL, and to ensure that Zeltiq is compensated for the damages BTL's false and misleading claims have caused.

CoolSculpting And CoolTone: Enormous Innovation, Enormous Success

10. Zeltiq's leadership in the medical aesthetics space dates back to its founding in 2005. Scientists working with Zeltiq created a path-breaking controlled-cooling fat reducing treatment, known by the scientific name of cryolipolysis, which Zeltiq commercialized under the name CoolSculpting.

11. In the CoolSculpting process, a healthcare professional uses an applicator connected to the CoolSculpting machine. When the applicator is applied to target areas of the body, it cools the fat cells below the skin, causing the

fat cells to freeze and die. The result is a natural, controlled elimination of the fat cells without affecting surrounding tissue. With CoolSculpting, patients have seen an improved body shape through a few brief office procedures, without anesthesia or pain. After each procedure, the patient is free to immediately resume normal activities.

12. CoolSculpting was initially cleared by the FDA in 2010 for the reduction of fat on the sides of the body. Over time, FDA clearances have expanded to include the treatment of visible fat bulges under the chin and jawline areas, as well as fat on the thigh, fat on the abdomen, bra fat, back fat, fat underneath the buttocks and fat on the upper arm.

13. CoolSculpting has achieved enormous success. Doctors and patients have embraced it in the United States and around the world. To date, CoolSculpting has been cleared or approved for use in more than 80 countries and has more than eight million treatments worldwide. CoolSculpting has more FDA-cleared areas than any other nonsurgical fat reduction devices and, with eight uniquely sized contours across five innovative applicators, CoolTone allows for customized treatment to the areas that bother patients the most. CoolSculpting is the treatment doctors use most for nonsurgical fat reduction. Through

CoolSculpting, Zeltiq built strong relationships with approximately 4,200 U.S. doctors' offices and medical spas that have purchased the device.

14. Zeltiq successfully launched its magnetic muscle stimulation ("MMS") product, CoolTone, in June of 2019. Commercially, CoolTone is a line extension of CoolSculpting – marketed to the same universe of HCPs and to patients who, like CoolSculpting patients, have an interest in achieving improved body appearance through non-invasive procedures. Scientifically, CoolTone employs a distinct device and procedure. CoolTone includes two applicators that deliver strong magnetic pulses to selected muscle areas, causing involuntary muscle contractions that strengthen, firm and tone the muscles. CoolTone's MMS technology is FDA-cleared for treatment of the abdomen, buttocks and thighs.

15. HCPs who already used CoolSculpting and have added CoolTone to their practices, can offer patients the benefit of two proven, FDA-cleared procedures from a single trusted company: CoolSculpting for fat reduction and CoolTone for muscle conditioning. The option to purchase the products together, along with the individual merits of CoolSculpting and of CoolTone, has led to increased success for CoolSculpting and strong early success for CoolTone.

BTL Tries To Catch Up Through False Advertising

16. BTL was late to the body contouring space, announcing the launch of its Vanquish Me device in 2013, three years after CoolSculpting was launched. In

2018, in another attempt to better compete with Zeltiq, BTL launched its Emsculpt product. The FDA clearances for Emsculpt are strictly limited to the toning and strengthening of certain specific muscle areas. Yet to catch up to Zeltiq's commercial success, BTL has regularly misstated and overstated what Emsculpt does and what it is approved to do. The false claims by BTL are directed both to HCPs and to patients. BTL's unlawful advertising falls into three distinct categories: False claims regarding Emsculpt's technical specifications, false claims of fat reduction and false claims of health and athletic improvements.

BTL Falsely Links Emsculpt's Technical Specifications To Efficacy Benefits

17. When Zeltiq advertises the magnetic intensity of CoolTone, its policy is to follow three important limitations.

18. First, Zeltiq's policy is to not advertise any specific linkage between magnetic intensity (or other technical specifications) and patient efficacy.

19. Second, Zeltiq advertises technical specifications, such as magnetic intensity, to HCPs who have medical and scientific training, but not to patients. For example, Zeltiq makes no reference to "50% greater magnetic intensity" on the patient-facing website at https://www.coolscultping.com/cooltone.

20. Third, when the magnetic intensity claim is made to HCPs, Zeltiq's policy is to include a clear disclaimer that the clinical significance of CoolTone's greater magnetic intensity has not been established.

21. BTL recklessly disregards all of these important limitations in its advertising for Emsculpt. Instead, BTL explicitly and falsely equates technical characteristics of Emsculpt with improved patient outcomes, both in claims directed to HCPs and in claims directed to patients, without appropriate disclaimers.

22. As one BTL advertisement directed to doctors states: "Double power within one: DoubleCore™ #Emsculpt applicators. Double winding coil architecture, designed to deliver higher output in larger spot size which enhances the ability to achieve sufficient flux of the magnetic field in the tissue. Simply speaking, deeper layers get treated with more energy for better and faster results. Dig in to bring your practice on top, with #Emsculpt."

23. This claim by BTL explicitly and falsely ties "higher output" (explained in a footnote as Emsculpt's "Magnetic Field Intensity") to "better and faster results." The references to "more," "higher," "better" and "faster" unmistakably are comparisons to CoolTone: As BTL asserts in its own complaint (Complaint ¶¶ 44, 46, 83), Emsculpt and CoolTone are the only two major competitors in MMS medical aesthetics products. Simply put, BTL itself does exactly what it falsely accuses Zeltiq of doing: It explicitly connects magnetic

intensity with clinical efficacy – "better and faster results" – despite the lack of any cited proof or FDA approval, for that purported connection.

24. Likewise, BTL's patient-facing Facebook page states that Emsculpt's "DoubleCore architecture allows delivering more energy into the deeper layers of the tissue." In that same Facebook post, BTL claims that "EMSCULPT Delivers 270% More Energy in ETA (Effective Treatment Area – Energy = Power x Area." These claims (and others like them) are obviously comparisons to CoolTone. They obviously are meant to – and do – signal to consumers that the cited technical specifications will lead directly to better results than are obtainable with CoolTone. There is no basis in fact for these claims.

BTL Falsely Advertises Emsculpt With Respect To Fat Reduction

25. BTL is FDA-cleared for the strengthening, toning and firming of muscles – and nothing else. BTL acknowledges as much in the fine print on the Emsculpt website. There, under the heading "FDA Clearances," BTL says:

> Emsculpt® is intended for improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. Strengthening, toning, and firming of buttocks, thighs, and calves. Improvement of muscle tone and firmness, for strengthening muscles in arms.

Notably absent is any reference to the reduction of fat as an FDA-approved use or a scientifically supported use.

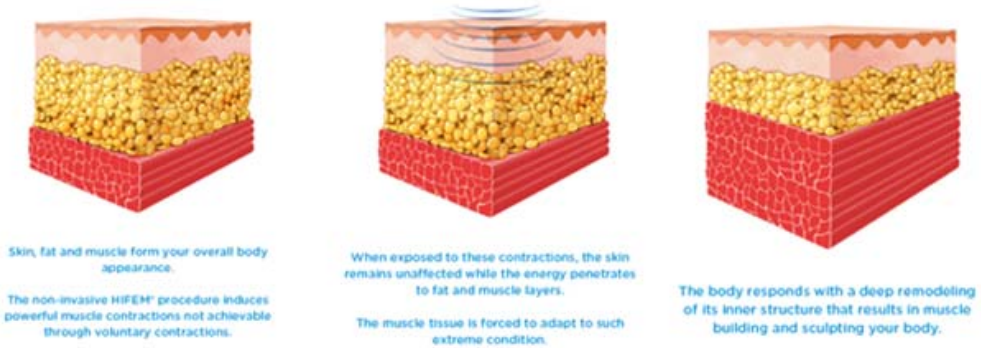
26. Zeltiq offers FDA-approved treatments for both fat (CoolSculpting) and muscle (CoolTone). The many HCPs who offer both CoolSculpting and CoolTone therefore can provide "one-stop shopping" to the many patients looking to treat both fat and muscle.

27. To attempt to compete with Zeltiq's increasingly successful CoolSculpting and CoolTone products, BTL has falsely promoted Emsculpt as a single device capable of treating both muscle and fat. The advertising for Emsculpt mixes and matches references to FDA-approved and unapproved uses in a way that is plainly intended to, and does, confuse the consumer into thinking that Emsculpt is FDA-approved both for treatment of fat and treatment of muscle. For example, BTL's patient-facing Facebook page for Emsculpt states (emphasis added):

> ***EMSCULPT builds muscle and kills fat cells.*** Coolsculpting covers a much smaller area in each treatment session than EMSCULPT. EMSCULPT actually increases overall basal metabolic rate by increasing muscle mass. Coolsculpting does not. ***Both [the EMSCULPT and CoolSculpting] devices are FDA cleared devices.***

28. In addition, on the patient-directed portion of the Emsculpt website, BTL displays the below images that show both a clear increase in size of the red layer of muscle tissue and a clear reduction in size of the yellow layer of fat after treatment with Emsculpt. The clear purpose and effect of the images is to falsely

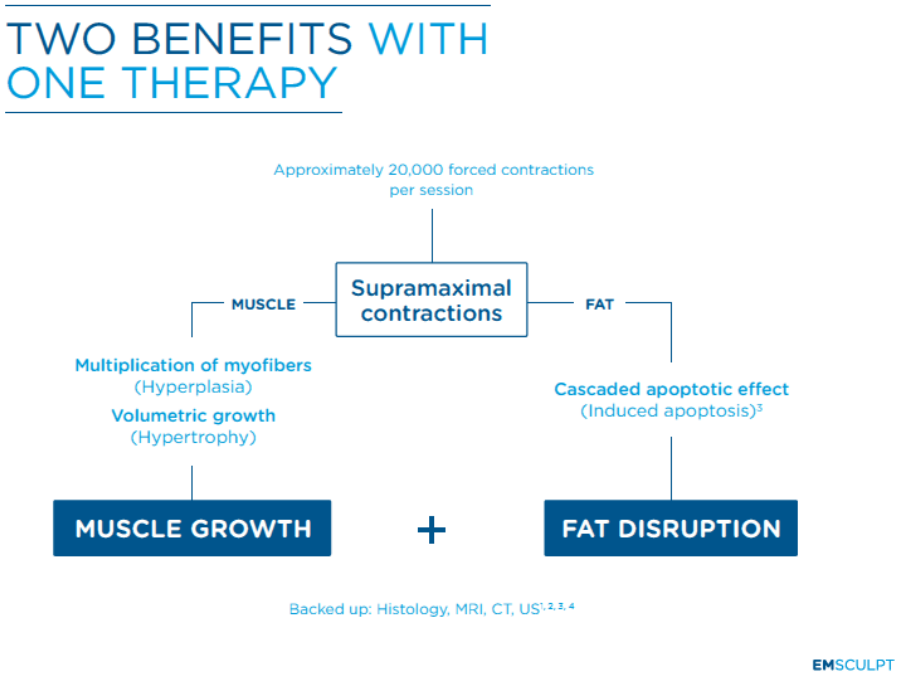
communicate to patients that Emsculpt has the same degree of regulatory approval, and efficacy, with respect to both muscle and fat.



(Image 1: pre-treatment) (Image 2: during treatment) (Image 3: post-treatment)

29. BTL not only makes false claims with regard to FDA recognition of Emsculpt's purported fat-reducing capacity, but also lacks any reliable substantiation for the underlying claims of fat reduction. BTL has widely broadcast the claim that Emsculpt causes a 19% reduction in fat. For example, in what is, on information and belief, an Emsculpt product brochure, BTL claims that Emsculpt leads to a 19% reduction in fat, as depicted below.

30. In that same product brochure, BTL touts that Emsculpt is "[t]he world's only procedure that simultaneously addresses both muscle & fat." Further, BTL claims that Emsculpt causes a "[c]ascaded apoptotic effect," that leads to "fat disruption," as depicted below. These claims, and others like them by BTL, do not have reliable scientific support.



31. As support for its fat reduction claims, BTL has cited to studies that do not, in fact, provide reliable scientific support. BTL points in one instance to a study where the sample size consisted of two subjects and the two subjects were pigs rather than people. BTL also cites to other studies that, while at least involving human subjects, have other flaws including limited sample sizes and high coefficients of variation that render their results questionable at best. BTL

has published no reliable study and, on information and belief, lacks any such study that could provide the legally required support for its false and misleading claims that Emsculpt reduces fat.

BTL Falsely Touts Emsculpt's Athletic Performance Benefits And Its Applicability To "All Patients"

32. BTL makes a remarkable series of claims for what Emsculpt will do for patients in their athletic lives – claims that are patently false and, indeed, nothing short of outrageous. In one ad, BTL states:

> More than 14k individuals will complete the LA marathon next month. To gain a last minute edge for a better time, or simply ensure you complete the marathon, discover #EMSCULPT. Emsculpt is a form of core conditioning that reduces the chances of all sorts of injuries as well as improves stability and balance.

Emsculpt is not indicated for improved race times for runners, nor has it been proven as any form of marathon training. Emsculpt is not "a form of core conditioning." As the Mayo Clinic notes (https://www.mayoclinic.org/healthy-lifestyle/fitness/in-depth/core-exercises/art-20044751), core exercises are those that "train the muscles in your pelvis, lower back, hips and abdomen to work in harmony. . . . Any exercise that involves the use of your abdominal and back muscles in coordinated fashion counts as a core exercise." Emsculpt does none of these things. Emsculpt has not been proven to "reduce[] the chances of all sorts of injuries," nor to "improve[] stability and balance."

33. Similarly, on its Facebook page, BTL states:

> EMSCULPT can be utilized for many reasons beyond aesthetics, such as for the treatment of low back pain, balance issues, to improve your golf game & any other issues that may benefit from improved core strength.

These claims too are, in a word, nonsense. Emsculpt is not indicated, FDA-cleared or -approved or proven to reduce low back pain, to improve one's golf game or (yet again) to improve balance or improve core strength generally.

34. BTL falsely touts Emsculpt as a substitute for exercise rather than (as would be accurate) a supplement to exercise. A patient testimonial in one of BTL's own promotional videos for Emsculpt states:

> You're laying there and it feels like you're doing a thousand crunches . . . By the time you drive to a gym, get undressed, do your workout – what are you doing to get these results? Stairstepper, lunges, squats, bands, TRX, running, cardio, diet – everything into that, you're given [with Emsculpt] at 30 minutes, 2 days a week for 2 weeks.

These claims are nonsense too. No body-contouring medical procedure can take the place of regular exercise and a healthy diet. Emsculpt is not indicated, FDA-cleared or -approved or proven to simulate 1,000 crunches, nor to take the place of any or all of the referenced exercises.

35. The false claims promoted by BTL do not just come out of the mouths of patients, but also the mouths of doctors. In a BTL promotional video for Emsculpt, one doctor states: "I think almost every patient will need this device

post [liposuction] procedure because it'll really finish the job." This claim too is patently false. BTL is not indicated, FDA-cleared or -approved, or proven as a post-liposuction treatment, much less as aftercare for "almost every patient" who has liposuction.

36. Another doctor states in the same video: "This is a device that fits all patients, whether they have just a little bit of fat or they need to improve their tone or their shape; it covers everything." This aggressive medical marketing of off-label usage for fat reduction contributes to BTL's campaign of blurring the distinctions between which uses of Emsculpt are FDA-cleared and which are not.

37. The claim of suitability for "all patients," like the claim of suitability for "almost every [post liposuction] patient," falsely disregards the substantial contraindications for Emsculpt. As one of BTL's own partner medical practices states (https://artofskinmd.com/cosmetic-procedures/body-contouring/emsculpt/):

> **Who is a poor candidate for EMSCULPT? Are there contraindications?**
>
> Patients with significant fat stores may not be ideal candidates for EMSCULPT. The HIFEM (High Intensity Focused Electro Magnetic) energy used to power EMSCULPT penetrates to about 7 cm. Those with thicker fat stores may not get as significant of muscle contraction, resulting in less results following treatment.
>
> Pregnant and nursing females should not undergo treatment with EMSCULPT.

> Women who are close to menstruation may find that it comes sooner or cramping is increased/intensified with EMSCULPT treatments, therefore we recommend not undergoing treatment during this time of the month.
>
> Possible contraindications to treatment include the following: Metal or electronic implants in the treatment area; Cardiac pacemakers; Implanted defibrillators; Implanted neurostimulators; Drug pumps; Malignant tumor; Hemorrhagic conditions; Epilepsy; Recent surgical procedures [presumably including liposuction].

These contraindications render BTL's claims that Emsculpt is suitable for "all" patients, or "almost every" liposuction patient, false and misleading.

FIRST CAUSE OF ACTION

False Advertising In Violation Of Lanham Act § 43(a)(1)(B), 15 U.S.C. § 1125(a)(1)(A)

Zeltiq repeats and incorporates by reference the allegations in the paragraphs above, as though fully set forth herein.

38. BTL's commercial advertising and promotional claims described above are false or misleading descriptions of fact, or false or misleading representations of fact, made in interstate commerce, that misrepresent the nature, characteristics and qualities of BTL's and Zeltiq's products in advertising and promotion, and that both deceive and have the capacity to deceive a substantial segment of relevant consumers and potential consumers for the parties' respective products.

39. These claims violate Section 43(a) of the Lanham Act, which provides in relevant part that a "person who, or in connection with any goods or services . . . uses in commerce any . . . false or misleading description of fact or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable to a civil action by any person who believes that he or she is likely to be damaged by such act."

40. BTL's commercial advertising and promotional claims actually deceived or have the tendency to deceive a substantial segment of BTL's audience, and BTL's deception is material in that it is likely to influence purchasing decisions.

41. BTL's commercial advertising and promotional claims have caused and are likely to cause damage to Zeltiq and the public and, unless restrained, will further damage Zeltiq and the public.

42. BTL's commercial advertising and promotional claims are causing immediate and irreparable competitive and commercial injury to Zeltiq, and to its goodwill and its reputation, that affects its ability to compete in the marketplace, and will continue to cause such injury unless enjoined by this Court.

43. On information and belief, BTL's acts of false advertising are willful, deliberate, and in bad faith.

44. Zeltiq has no adequate remedy at law.

45. Zeltiq is entitled to injunctive relief and to recover up to three times its actual damages and/or an award of BTL's profits, as well as costs and Zeltiq's reasonable attorneys' fees under 15 U.S.C. §§ 1116 and 1117.

SECOND CAUSE OF ACTION

Unfair Trade Practices In Violation Of Delaware's Uniform Deceptive Trade Practices Act (6 *Del. C.* § 2532)

Zeltiq repeats and incorporates by reference the allegations in the paragraphs above, as though fully set forth herein.

46. BTL's commercial advertising and promotional claims described above are false, misleading and deceptive advertising claims concerning the sale of the Emsculpt product.

47. BTL's commercial advertising and promotional claims described above are false and misleading representations of fact that disparage Zeltiq's CoolTone product.

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ZELTIQ'S PRAYER FOR RELIEF

WHEREFORE, Zeltiq respectfully requests that the Court:

1. Enter judgment in favor of Zeltiq on all counts of the Complaint and on Zeltiq's Counterclaims;

2. Enter an order permanently enjoining Counter-Claim Defendant BTL, its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, from directly or indirectly falsely or misleadingly advertising or promoting Emsculpt;

3. Enter an order requiring that BTL take corrective action to correct any erroneous impression persons may have derived concerning the qualities of the Emsculpt product, the efficacy of the Emsculpt product, and the relative efficacy of the Emsculpt product as compared to that of competitors, including without limitation, the placement of corrective advertising;

4. Enter an order requiring BTL pay Zeltiq damages in an amount sufficient to compensate Plaintiff for injury it has sustained as a consequence of BTL's unlawful acts;

5. Enter an order requiring BTL pay Zeltiq damages in the amount of Zeltiq's actual and consequential damages resulting from BTL's false and misleading advertisements and marketing and unfair competition pursuant to the Lanham Act (15 U.S.C. § 1117(a)) and the DTPA (6 *Del. C.* § 2533);

6. Enter an order finding that this is an exceptional case and requiring BTL to pay Zeltiq additional damages equal to three times the actual damages awarded Zeltiq pursuant to the Lanham Act (15 U.S.C. § 1117(a));

7. Enter an order finding that this case is an exceptional case and requiring BTL to pay all of Zeltiq's litigation expenses, including reasonable attorneys' fees and the cost of this action, pursuant to the Lanham Act (15 U.S.C. § 1117), 17 U.S.C. § 505, the DTPA (6 *Del. C.* § 2533), and other applicable laws; and

8. Grant Zeltiq such other relief as the Court may deem just and proper.

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ANSWER

GENERAL DENIAL

Except as otherwise expressly admitted herein, Zeltiq denies each and every allegation contained in the Complaint, including, without limitation, any allegations contained in the preamble, headings, subheadings, footnotes or exhibits of the Complaint, and specifically denies any liability to BTL. Pursuant to Rule 8(b) of the Federal Rules of Civil Procedure, allegations in the Complaint to which no responsive pleading is required shall be considered denied. Zeltiq expressly reserves the right to seek to amend and/or supplement this Answer as may be necessary.

RESPONSES TO PLAINTIFF'S ALLEGATIONS

1. Deny, except admit that BTL purports to bring this case as a civil action under the Lanham Act (15 U.S.C. § 1125(a)) and Delaware's Uniform Deceptive Trade Practices Act (6 *Del. C.* § 2532).

2. Deny having knowledge or information sufficient to form a belief as to the truth of the allegations, except admit that the launch of CoolTone was publicly announced in June 2019, Zeltiq began accepting orders for CoolTone in June 2019, and that the CoolTone device became available to HCPs in December 2019.

3. Deny, except admit that advertising for CoolTone began in June 2019, prior to the commercial availability of the device, and refer to the advertising for its content, which speaks for itself.

4. Deny, except admit that Zeltiq began accepting orders for CoolTone in June 2019, and that the CoolTone device became available to HCPs in December 2019.

5. Deny.

6. Deny, except admit that Zeltiq supplies covers, a/k/a bonnets, for CoolTone applicators and instructs clinicians to use either the bonnet or the patient's clothing as a barrier between the applicator and the skin. Aver that the purpose of the bonnet is to avoid having non-biocompatible materials, *i.e.*, the surface of the applicator, come into contact with patients' skin; deny in particular that the purpose of the applicator is to avoid burning patients.

7. Deny.

8. Deny.

9. Deny, and refer to the contents of Zeltiq's advertising for CoolTone, which speak for themselves and include a clear statement that the clinical significance of the magnetic intensity has not been established; except, deny having knowledge or information sufficient to form a belief as to the truth of

BTL's allegations regarding the results of its own testing, and admit that the higher the induced electrical current, the stronger the muscle contraction, and that induced electrical current is proportional to the rate of change of magnetic flux density of the generated magnetic pulses, so the faster the rate of change of the pulses' magnetic flux density, the more electrical current is induced in the patient's target tissue.

10. Deny, and refer to the contents of Zeltiq's advertising for CoolTone, which speak for themselves and include a clear statement that the clinical significance of the magnetic intensity has not been established.

11. Deny, and refer to the letters identified in paragraph 11, the contents of which speak for themselves.

12. Deny.

13. Deny having knowledge or information sufficient to form a belief as to the truth of the allegations.

14. Refer to the separate motion to dismiss filed by Allergan plc for its contents, which speak for themselves.

15. Refer to the separate motion to dismiss filed by Allergan USA, Inc. for its contents, which speak for themselves.

16. Refer to the separate motion to dismiss filed by Allergan, Inc. for its contents, which speak for themselves.

17. Deny, except admit that Zeltiq was acquired in 2017 and exists as an indirect, wholly-owned subsidiary of Allergan plc.

18-24. These paragraphs state legal conclusions as to which no response is required. To the extent these paragraphs require a response, deny as to Zeltiq, except admit that Zeltiq is subject to personal jurisdiction and venue in this District.

25. Deny, and refer to the referenced exhibit for its full contents, which speak for themselves, except admit that BTL is and has been a company in the aesthetics space, including in the United States for approximately 10 years or more.

26. Deny, and refer to the referenced exhibit for its full contents, which speak for themselves, except admit that BTL is and has been a company in the aesthetics space, including in the United States for approximately 10 years or more.

27. Deny, except admit that BTL markets devices, including Emsculpt, in the United States, and refer to the FDA clearances for Emsculpt for their full contents, which speak for themselves.

28. Deny, except admit that BTL markets devices, including Emsculpt, in the United States, and refer to the FDA clearances for Emsculpt for their full contents, which speak for themselves.

29. Deny, and refer to the referenced exhibit for its full contents, which speak for themselves, except admit that BTL markets different applicators for Emsculpt to be used on different areas of the body.

30. Deny, and refer to the referenced exhibits for their full contents, which speak for themselves, and aver that the cited references to Emsculpt as "[taking] the aesthetics industry by storm," having "transformed treatment protocols" and being "revolutionary" all come from BTL's own press releases.

31. Deny, and refer to the referenced exhibits for their full contents, which speak for themselves.

32. Deny, and refer to the referenced FDA clearances for their full contents, which speak for themselves.

33. Deny, except admit that the acquisition of Zeltiq was completed in 2017, and refer to the press release describing the acquisition, the contents of which speak for themselves.

34. Deny, and refer to the CoolTone website for the full contents thereof, which speak for themselves.

35. Deny, and refer to the referenced exhibit for the full contents thereof, which speak for themselves.

36. Deny, and refer to the CoolTone user manual for the full contents thereof, which speak for themselves.

37. Deny.

38. Deny, except admit that the two applicators included in Zeltiq's CoolTone product are the same size and shape; the size and shape of the applicators to be used do not change based on the target treatment area.

39. Admit.

40. Deny, and refer to the June 24, 2019 press release, the contents of which speak for themselves.

41. Deny.

42. Deny, except admit that, like Emsculpt, CoolTone was approved through the 510(k) submission for the clearance of CoolTone, and refer to the 510(k) submission for the full contents thereof, which speak for themselves, and refer to the full contents of the FDA's documentation for the 510(k) process, which speak for themselves.

43. Deny, and refer to the full contents of Exhibits 10 and 12, which speak for themselves.

44. Deny, and refer to the full contents of Exhibit 15, which speak for themselves, except admit that Emsculpt is CoolTone's principal competitor and is the only other device on the market used to tone the abdomen, buttocks and legs.

45. Deny, and refer to the full contents of Exhibits 10 and 12, which speak for themselves.

46. Deny, and refer to the full contents of Exhibit 16, which speak for themselves.

47. Deny, and refer to the full contents of Exhibits 16 and 17, which speak for themselves.

48. Deny, and refer to the full contents of the subject video chat, which speak for themselves.

49. Deny having knowledge and information sufficient to form a belief as to the truth of the allegations, except refer to the full contents of the subject press releases, which speak for themselves.

50. Deny, except admit that greater magnetic intensity alone has not been proven to result in better clinical efficacy, as noted in the prominent disclaimer in Zeltiq's advertising of CoolTone to HCPs.

51. To the extent the allegations contained in paragraph 51 state a legal conclusion, no response is required. To the extent that a response is required,

deny, except admit that Zeltiq sells the CoolTone product to physicians in many states, including Delaware and Pennsylvania, and refer to the full contents of the referenced websites, which speak for themselves.

52. Deny, and refer to the full contents of the subject advertisement, which speak for themselves.

53. Deny, except admit that clinicians are instructed that either a bonnet over the CoolTone applicator, or the patient's clothing, should separate the applicator surface from the patient's skin during patient treatment; deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in BTL's complaint; deny having knowledge or information regarding the nature or results of such testing. Zeltiq will provide further information about the nature of the testing conducted for CoolTone once an appropriate protective order is in place in this litigation.

54. Deny having knowledge or information regarding the nature or results of testing conducted by BTL.

55. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided

to Zeltiq beyond the self-serving summaries in BTL's complaint; deny having knowledge or information regarding the nature or results of such testing.

56. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing. Zeltiq will provide further information about the nature of the testing conducted for CoolTone once an appropriate protective order is in place in this litigation.

57. Deny, and refer to the subject CoolTone marketing materials and instructions for their full contents, which speak for themselves, except admit that clinicians are instructed that either the bonnet or the patient's clothing should separate the patient's skin from the surface of the CoolTone applicator.

58. Deny, and refer to the full contents of Zeltiq's claims for CoolTone, which speak for themselves, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

59. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided

to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

60. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

61. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

62. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

63. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

64. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

65. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

66. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

67. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

68. Deny, and refer to the companies' respective FDA clearances for their full contents, which speak for themselves.

69. Admit.

70. As to the first sentence, deny. As to the remaining sentences, admit.

71. As to the first sentence, deny and refer to the full contents of salesforce communications, which speak for themselves. As to the second sentence, admit.

72. Deny, and refer to the full contents of the subject advertising, which speak for themselves.

73. Deny, except note that the allegations of this paragraph appear to be based on patient reports to BTL and testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such reports or testing.

74. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

75. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

76. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

77. Deny, except note that the allegations of this paragraph appear to be based on testing conducted by BTL, about which no information has been provided to Zeltiq beyond the self-serving summaries in the Complaint; deny having knowledge or information regarding the nature or results of such testing.

78. Deny.

79. This paragraph states a legal conclusion, as to which no response is required. To the extent that a response is required, deny.

80. Deny, except admit that FDA clearance for CoolTone was received in June 2019, and that Zeltiq took orders for CoolTone before the device became available in December 2019.

81. Deny, and refer to the subject websites for their full contents, which speak for themselves.

82. Deny, and refer to the subject websites for their full contents, which speak for themselves.

83. Deny, except admit as to BTL and Zeltiq.

84. Deny, except admit as to BTL and Zeltiq.

85. Deny, and refer to the subject websites for their full contents, which speak for themselves, except admit that Zeltiq, as part of the Allergan family of companies, has a strong history and reputation in the aesthetics field that influences customer purchase decisions.

86. Deny.

87. Deny.

88. Deny.

89. Deny.

90. Deny.

91. Zeltiq repeats and re-alleges each of its responses to paragraphs 1-90 as though fully set forth herein.

92. Deny, and refer to the referenced exhibits for their full contents, which speak for themselves.

93. Deny.

94. Deny.

95. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

96. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny, except admit that Zeltiq has sold CoolTone in multiple states, including Delaware.

97. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

98. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

99. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

100. Zeltiq repeats and re-alleges each of its responses to paragraphs 1-99 as though fully set forth herein.

101. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny, and refer to Delaware's DTPA and the cited case for the full contents thereof.

102. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

103. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny, and refer to the referenced exhibits for their full contents, which speak for themselves.

104. Deny.

105. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

106. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

107. Deny, except, as to Zeltiq, admit.

108. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

109. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

110. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

111. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

112. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

113. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

114. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny.

ANSWER TO PRAYER FOR RELIEF

115. This paragraph states a legal conclusion as to which no response is required. To the extent a response is required, deny that BTL is entitled to the relief requested, or to any other relief.

AFFIRMATIVE DEFENSES

Zeltiq sets forth below affirmative defenses. Each affirmative defense is asserted as to all claims asserted against Zeltiq in the Complaint. By setting forth these defenses, Zeltiq does not assume the burden of proving any fact, issue or element of a claim where such burden properly belongs to BTL. Zeltiq does not in any way waive or limit any defenses which are or may be raised by its denials and averments. These defenses are pled in the alternative, to preserve the rights of Zeltiq to assert such defenses and are without prejudice to the ability of Zeltiq to raise other and further defenses.

1. BTL's claims are barred, in whole or in part, for failure to state a claim upon which relief can be granted.

2. BTL's claims are barred because it has suffered no harm or damages.

3. BTL's claims are barred because the referenced advertising by Zeltiq was not the cause, legal or proximate, of BTL's alleged injuries, to the extent that BTL suffered any injuries.

4. BTL's claims are barred, in whole or in part, because BTL failed to mitigate damages, to the extent that BTL suffered any damages.

5. BTL's claims are barred, in whole or in part, by the doctrines of waiver and/or estoppel.

6. BTL's claims are barred, in whole or in part, by the doctrine of unclean hands.

7. Zeltiq reserves the right to assert additional affirmative defenses, based upon further investigation and discovery.

[signature page follows]

Dated: April 20, 2020

Respectfully submitted,

REED SMITH LLP

/s/ Brian M. Rostocki

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